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(54) **HEMOSTATIC PLUG**

HäMOSTATISCHER STOPFEN

BOUCHON HEMOSTATIQUE

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Description

Background of the Invention

[0001] This invention relates generally to a method of making a hemostatic plug for placement at a site where hemostatic treatment is indicated such as a puncture wound, and in particular to a method for making the plug wherein the plug comprises a rolled sheet of a hemostatic material which tends to unfurl after placement in a wound cavity and thereby fill the wound cavity.

[0002] Hemostatic treatment can be indicated at a variety of sites where a patient exhibits bleeding. An example of such a site occurs when performing angioplasty, angiography, or other procedures requiring establishment of an entry into a blood vessel of a patient. After such a procedure, it is necessary to effectuate closure of the resulting puncture wound upon withdrawal of instrumentation employed in performing the medical procedure and in maintaining the puncture entry of the blood vessel. Traditional approaches employed to promote wound closure include hand pressure, pressure bandages, clamps and the like to maintain pressure over the region of the wound for a time sufficient to stop bleeding. U.S. Patent Nos. 4,852,568, 4,890,612, 4,838,280 and 4,936,835 disclose the use of a plug made of a solid mass of a hemostatic material for placement at the wound site. Co-pending Application Serial No. 912,921, filed July 13, 1992, corresponding to EP-A-610241, published after priority date of the application, and assigned to the same assignee as the present invention, teaches a hemostatic plug having an opening throughout its longitudinal axis so that it can be accommodated and placed in coaxial relationship with a novel implant introducer device described and claimed in that application. Except for the opening along its longitudinal axis, the plug described in the co-pending application is constructed from a solid mass of hemostatic material. European Patent Application EP-A-149155 which is used as basis for the preamble of the independent claims 1 and 9, relates to a tampon which is used to control bleeding. This application also relates to a method of making a tampon by rolling a sheet of material a plurality of times onto a generally cylindrical forming tool to produce the tampon.

[0003] Because speed is of the essence in closing a puncture wound to thereby stop bleeding, it is advantageous to have hemostatic material whose configurations and characteristics cause rapid and effective wound cavity occupation and blood flow stoppage.

[0004] It is therefore a primary object of the present invention to provide a method of making a hemostatic plug which rapidly fills a wound cavity and which provides advantageous surface area presentment to promote hemostasis.

[0005] Another object of the present invention is to provide a method of making a hemostatic plug constructed from a sheet of a hemostatic material rolled upon a cylindrical forming tool whereby the plug subsequently unfurls in a wound cavity to thereby fill the cavity arid increase cavity pressure while presenting advantageous surface area for fluid absorption and blood flow cessation.

[0006] These and other objects of the present invention will become apparent throughout the description which now follows.

Summary of the Invention

[0007] The present invention as defined in independent claims 1 and 9 relates to a method of making a hemostatic plug for placement at a site where hemostatic treatment is indicated and to a hemostatic plug. The method comprises rolling a sheet of hemostatic material a plurality of turns on a generally-cylindrical forming tool to thereby produce a rolled hemostatic plug having an opening therethrough along its longitudinal axis. It is to be understood that, throughout this application, the term "single density plug" refers to the density characteristics of the initial sheet of hemostatic material used to construct the plug. Because the plugs produced according to the present invention are rolled sheets rather than a solid mass of hemostatic material, they unfurl when situated in a wound cavity and subjected to blood and tissue fluid emitting from the wound. The plugs thereby provide increased surface area and correspondingly more rapid efficacy within the wound cavity to promote blood flow cessation and healing.

[0008] A typical site where hemostatic treatment is indicated and for which a plug produced according to the present invention can be employed is a puncture wound resulting from an angioplasty or angiography procedure. Specifically, the wound includes an entry penetration of an artery and a tissue channel leading from the surface of a patient's skin to the site of artery penetration. Thus, the plug must be sized to fit within the tissue channel so that its distal end is adjacent to the artery penetration site. A care provider can choose, for example, a low density plug, a preferred medium density plug, or a high density plug. A low density plug has a greater absorption rate, yet less potential compression force. Conversely, the high density plug typically has a lower absorption rate and a higher potential compression force. Where typically both a relatively normal absorption rate and pressure application are desired, a care provider will employ a medium density plug which provides characteristics of favorable absorption as well as pressure.

[0009] The preferred method of making the preferred single density plug is accomplished by rolling a sheet of hemostatic material on a generally cylindrical forming tool, preferably followed by longitudinal compression of the rolled sheet while on the forming pin, to form the plug. Employment of the forming tool in the manufacture of the plug results in an opening along the longitudinal axis of the plug so that the plug can be delivered to the

wound site on a guidewire or other cylindrical placement device.

[0010] Plugs produced according to the instant invention provide versatility in the treatment of puncture wounds as above described by providing to a wound cavity a maximized hemostatic surface area to promote hemostasis and wound healing. Both the penetration site of the artery and the tissue channel leading to the artery are thereby effectively treated through fluid and blood absorption, hemostatic action, and pressure application to aid in the healing process of the wound.

Brief Description of the Drawings

[0011]

Figure 1 is an enlarged perspective view of a single density hemostatic plug for closing a puncture wound;

Figure 2 is an elevation view of a single density sheet of hemostatic material rolled on a forming pin to thereafter form the plug of Figure 1;

Figures 3a and 3b are side elevation views, partially in section, showing formation of a hemostatic plug within a forming block;

Figures 4a-4d are side elevation views illustrating removal of the plug of Figure 1 from the forming pin; and

Figure 5 is an enlarged perspective view of a single density hemostatic plug having lateral openings along its length.

Detailed Description of the Invention

[0012] Referring to Figure 1, a single density hemostatic plug 10 is shown. Constructed according to the present invention, the plug 10 is a compressed rolled sheet 12 of hemostatic material 14 sized to fit the dimensions of a puncture wound. The distal end 15 of the plug 10 is tapered at about 10 degrees to thereby provide both better movement through a wound channel and an improved tactile sense when the distal end 15 reaches the artery site. Taper magnitude preferably can be from 10 degrees to 45 degrees. Thickness of the compressed sheet 12 is preferably between 0.0254 and 0.0508 cm (0.010 and 0.020 inch), and most preferably between 0.036 and 0.0406 cm (0.014 and 0.016 inch), while the diameter of the plug 10 can be chosen as required by the number of times the sheet 12 is rolled upon itself. Typical diameter choices of plugs 10 are 1,67-2,3 mm 5-7 French and 2,3-3 mm 7-9 French, but, of course, can be manufactured as desired. In the preferred single density plug 10, here shown, the plug 10 is constructed of collagen and has a diameter of 1,67-2,3 mm 5-7 French. The characteristics of the sheet 12 prior to plug construction are as follows: density --0.0058 grams per square cm (0.0373 grams per square inch); weight -- 0.06 gram; width --1.78 cm (0.70 inch); and length -- 5.84 cm (2.30 inch). The collagen here employed is that as is currently available from Vitaphore Corporation, Menlo Park, California, under the name "Collastat." As is recognized by the skilled artisan, however, any hemostatic sheet material can be employed to achieve the objectives here described. Non-limiting additional examples of such materials known in the art to have hemostatic activity include hemostatic gelatin, modified polyglycolic acid-based material, and thrombin. Thus, any hemostatic material can be employed in practicing the present invention so long as that material is capable of being formed into a thin sheet which then can be rolled on a generally cylindrical forming tool. An opening 16 extends substantially along the longitudinal axis of the plug 10 for its entirety. The opening 16 accommodates a guidewire (not shown) or other cylindrical placement device for positioning the plug 10 at a wound site.

[0013] Of course, weights and physical dimensions ban be chosen as would be recognized by a skilled artisan to produce a plug having properties as desired by the user.

[0014] The following procedure details the methodology employed in constructing the single density hemostatic plug 10 as shown in Figure 1. In particular, with respect to the single density plug 10, a piece of hemostatic material approximately 6.35 cm by 5.08 cm (2.5 inch by 2.0 inch) is compressed as with a roller mill to a thickness of 0.036 to 0.041 cm (0.014 to 0.016 inch). The weight (W_b) of the resulting thin piece is then determined and its density (D_b) in grams per square inch is determined according to the formula $D_b = W_b/A_b$, where A_b is the surface area of the thin piece. Preferred plug depth, (S_w), which is actually the width of a sheet to be rolled to form the plug, of the plug 10 is from 1.65 cm (0.65 inch) to 1.91 cm (0.75 inch), while total weight (W_s) is preferred to be about 0.06 gram. Sheet length (S_l) is then determined according to the formula $S_l = W_s/(D_b \times S_w)$. In the preferred embodiment the hemostatic material has a density of 0.0058 gcm^{-2} (0.0373 grams per square inch), a width (S_w) of 1.78 cm (0.70 inch) and a length of 5.84 cm (2.30 inch). The sheet should be cut immediately after being compressed by the aforementioned mill rolling since thickness can be regained over time. Cutting should be accomplished with a sheering device such as scissors since straight edge or blade cutting does not result in a clean cut.

[0015] A generally cylindrical forming tool, here a forming pin 32, having a uniform diameter except for a conical end 34 is used as a spool upon which the sheets are rolled. The conical end 34 of the forming pin 32 is provided so that subsequent forming tools as described later which slide on the forming pin 32 can be easily introduced. Formation of a single density plug 10 is accomplished by hand by rolling the sheet 12 tightly on the pin 32, as shown in Figure 3, with each turn of the sheet's edges in alignment with the edges of all other

turns. It is to be noted that, due to the mill rolling, one side of the sheet 12 has a satin dull finish while the other side has a shiny appearance. The sheet 12 should be rolled on the forming pin so that the shiny side is exposed. After rolling a sheet 12 on the forming pin 32, the resulting single density plug precursor 36 is smoothed as with a paddle to blend any roughened transitions.

[0016] While the term "plug precursor" has been used above, this term is chosen merely to indicate that additional manufacturing steps can be taken as described below to achieve construction of a final preferred plug device. However, it is to be understood that the "plug precursors" described above are operational and have utility as hemostatic plugs without further modification.

[0017] By longitudinally compressing a precursor plug as defined above, the resulting plug can longitudinally expand after placement at a wound site to a depth approximating the dimension of the precursor plug. In order to achieve this preferred longitudinal compression of the precursor plug 36 rolled on the forming pin 32 to thereby produce the hemostatic plug 10, certain forming tools are employed as illustrated in Figures 3a and 3b. In addition to the forming pin 32 already described, these tools include a forming block 40, a plug pusher 42, a compression tube 44, a vertical press 46 and a vice 47 to hold the block 40 in place. The forming block is two piece and has at least one cylindrical cavity 48 therein where the precursor plug 36 still rolled on the forming pin can reside. Once the precursor plug 36 is placed within the cavity, the two-piece block is assembled and mounted in the vice 47 situated in alignment with and beneath the compression tube 44 extending from a vertical press 46. The plug pusher 42 is slid onto the protruding portion of the forming pin 32 and advanced so that its distal end is juxtaposed with the end of the precursor plug situated within the block 40. The protruding portion of the forming pin 32 is aligned with the compression tube 44 which extends from the vertical press 46 so that the compression tube 44 will slide onto the forming pin 32 and into the cavity 48 of the forming block 40 when the vertical press 46 is activated. The compression tube 44 is then advanced over the forming pin 32 to contact the plug pusher 42 and is driven into the cavity 48 of the forming block 40 a depth necessary to compress the precursor plug 36 as desired to thereby form the completed hemostatic plug 10. The end 50 of the cavity 48 within the forming block 40 is shaped to provide the taper to the distal end 15 of the completed plug 10. Generally, the precursor plug 36 is compressed to about 50% of the original length to result in a length (depth) of about 1 cm, which represents a usual desired distance proximally from the site of arterial penetration. Of course, any length is attainable by varying the dimensional parameters as recognized by a skilled artisan. Thereafter, the forming block 40 is opened and the resultant hemostatic plug 10, plug pusher 42 and forming pin 32 are removed. As shown in Figures 4a-4d, a stripping tube 49 is then placed onto the forming pin 32 at its conical end 34 and is advanced against the plug pusher 42 to thereby push the plug pusher 42 and adjacent hemostatic plug 10 off of the forming pin 32. The plug pusher 42 then falls away and construction of the preferred hemostatic plug 10 is complete.

[0018] Figure 5 illustrates a third embodiment of a hemostatic plug 52 which is identical to the plug 10 of Figure 1 except for having a plurality of holes 54 therein to thereby provide more immediate surface area availability for blood and fluid absorption. The holes 54 are placed in the plug 52 with a sharp instrument such as a pin or a stamping operation subsequent to longitudinal compression of the precursor plug as described above.

[0019] Delivery and use of a hemostatic plug is fully described in the incorporated, commonly assigned patent application referenced. Briefly, in relation to each of the plugs of the present invention, such plug is delivered to the site of the blood vessel puncture by way of a coaxial delivery tool which reaches the puncture site on a guidewire already in place. Upon reaching the wound site, the plug is released from the delivery tool and the tool, guidewire and any additional apparatus at the wound site are withdrawn. The rolled plug is immediately subjected to blood and tissue fluid which cause the plug to unfurl or unroll to the boundaries of the wound cavity and thereby fill the wound cavity. This rolled feature of the plug provides two major benefits: it causes rapid occupation of the wound cavity upon unrolling, and it presents a large surface area after such unrolling for blood and tissue fluid contact. The former benefit results in quick fluid absorption and resultant pressure against the wound. The latter benefit, large surface area, results in more rapid hemostasis to thereby aid in blood flow cessation.

[0020] This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself as defined in the claims hereafter.

Claims

1. A method of making a hemostatic plug (10) for placement at a site where hemostatic treatment is indicated, said method comprising rolling a sheet (12) of a hemostatic material of a predetermined length a plurality of turns onto a generally cylindrical forming tool (32) to thereby produce a rolled hemostatic plug (10) having an opening (16) therethrough along the longitudinal axis thereof, and

thereafter removing the rolled hemostatic plug (10) from the forming tool (32), **characterized** in that the method comprises a longitudinal compression of the rolled hemostatic plug (10) prior to its removal from the forming tool (32), such that the hemostatic plug is of a compressed length less than the predetermined length dimension.

2. A method as claimed in Claim 1 wherein the longitudinal compression includes provision of a taper (15) to the distal end of the plug (10) at an angle of from 10 degrees to 45 degrees.

3. A method as claimed in Claim 1 or 2 wherein the hemostatic material is chosen from the group consisting of collagen, hemostatic gelatin, modified polyglycolic acid-based material and thrombin.

4. A method as claimed in Claim 3 wherein the hemostatic material is collagen.

5. A method as claimed in Claim 4 wherein the thickness of the sheet of collagen is from 0.0254 cm (0.010 inch) to 0.0508 cm (0.020 inch).

6. A method as claimed in Claim 5 wherein the thickness is from 0.0356 cm (0.014 inch) to 0.0406 cm (0.016 inch).

7. A method as claimed in Claim 4 wherein the density of the sheet of collagen is from 0.0050 to 0.0065 gcm^{-2} (0.032 to 0.042 gram per square inch).

8. A method as claimed in Claim 7 wherein the density of the sheet of collagen is from 0.0057 to 0.0059 gcm^{-2} (0.037 to 0.038 grams per square inch).

9. A hemostatic plug for placement in a wound site where hemostatic treatment is indicated, the plug comprising at least one sheet of a hemostatic material of a predetermined length dimension, said sheet being rolled upon itself a plurality of times to create a tubular structure, characterized in that said tubular structure is of a compressed length less than said predetermined length dimension, and having an opening along a longitudinal axis for its entire compressed length.

10. A hemostatic plug as claimed in Claim 9 wherein one end of said tubular structure is tapered at an angle of from 10 degrees to 45 degrees.

11. A hemostatic plug as claimed in claim 9 or 10 wherein the hemostatic material is chosen from the group consisting of collagen, hemostatic gelatin, modified polyglycolic acid-based material and thrombin.

12. A hemostatic plug as claimed in Claim 11 wherein the hemostatic material is collagen.

13. A hemostatic plug as claimed in Claim 9 wherein the plug is constructed of a single sheet of hemostatic material having substantially a single density.

14. A hemostatic plug as claimed in Claim 13 wherein the hemostatic material is collagen having a density from 0.0050 to 0.0065 gcm^{-2} (0.032 to 0.042 gram per square inch).

15. A hemostatic plug as claimed in Claim 14 wherein the collagen has a density from 0.0057 to 0.0059 gcm^{-2} (0.037 to 0.038 gram per square inch).

Patentansprüche

1. Verfahren zum Herstellen eines hämostatischen Stopfens (10) zum Anordnen an einer Stelle, an der eine hämostatische Behandlung angezeigt ist, wobei das Verfahren das Rollen einer Bahn (12) aus einem hämostatischen Material mit einer vorgegebenen Länge mit mehreren Wicklungen auf ein im allgemeinen zylindrisches Formwerkzeug (32), um dadurch einen aufgerollten hämostatischen Stopfen (10) mit einer entlang seiner Längsachse durch ihn verlaufenden Öffnung (16) herzustellen, und das danach erfolgende Entfernen des aufgerollten hämostatischen Stopfens (10) vom Formwerkzeug (32) aufweist, dadurch gekennzeichnet, daß das Verfahren eine Längskompression des aufgerollten hämostatischen Stopfens (10) vor seiner Entfernung vom Formwerkzeug (32) aufweist, so daß der hämostatische Stopfen eine komprimierte Länge hat, die geringer ist als die vorgegebene Längenabmessung.

2. Verfahren nach Anspruch 1, wobei die Längskompression das Vorsehen einer Verjüngung (15) am distalen Ende des Stopfens (10) unter einem Winkel von 10 bis 45 Grad aufweist.

3. Verfahren nach Anspruch 1 oder 2, wobei das hämostatische Material aus Kollagen, hämostatischer Gelatine, einem auf modifizierter Polyglykolsäure beruhenden Material oder Thrombin besteht.

4. Verfahren nach Anspruch 3, wobei das hämostatische Material Kollagen ist.

5. Verfahren nach Anspruch 4, wobei die Dicke der Kollagenbahn von 0,0254 cm (0,010 Zoll) bis 0,0508 cm (0,020 Zoll) reicht.

6. Vefahren nach Anspruch 5, wobei die Dicke von 0,0356 cm 0,014 Zoll) bis 0,0406 cm (0,016 Zoll) reicht.

7. Verfahren nach Anspruch 4, wobei die Dichte der Kollagenbahn von 0,0050 bis 0,0065 gcm^{-2} (0,032 bis 0,042 Gramm je Quadratzoll) reicht.

8. Verfahren nach Anspruch 7, wobei die Dichte der Kollagenbahn von 0,0057 bis 0,0059 gcm^{-2} (0,037 bis 0,038 Gramm je Quadratzoll) reicht.

9. Hämostatischer Stopfen zum Anordnen in einer Wundstelle, in der eine hämostatische Behandlung angezeigt ist, wobei der Stopfen wenigstens eine Bahn eines hämostatischen Materials mit einer vorgegebenen Längenabmessung aufweist, und die Bahn unter Erzeugung einer rohrförmigen Struktur mehrere Male auf sich selbst gerollt ist, dadurch gekennzeichnet, daß die komprimierte Länge der rohrförmigen Struktur geringer ist als die vorgegebene Längenabmessung und daß sie eine Öffnung aufweist, die entlang einer Längsachse über ihre ganze komprimierte Länge verläuft.

10. Hämostatischer Stopfen nach Anspruch 9, wobei sich ein Ende der rohrförmigen Struktur unter einem Winkel von 10 bis 45 Grad verjüngt.

11. Hämostatischer Stopfen nach Anspruch 9 oder 10, wobei das hämostatische Material aus Kollagen, hämostatischer Gelatine, einem auf modifizierter Polyglykolsäure beruhenden Material oder Thrombin besteht.

12. Hämostatischer Stopfen nach Anspruch 11, wobei das hämostatische Material Kollagen ist.

13. Hämostatischer Stopfen nach Anspruch 9, wobei der Stopfen aus einer einzigen Bahn eines hämostatischen Materials besteht, das im wesentlichen eine einzige Dichte aufweist.

14. Hämostatischer Stopfen nach Anspruch 13, wobei das hämostatische Material Kollagen mit einer Dichte von 0,0050 bis 0,0065 gcm^{-2} (0,032 bis 0,042 Gramm je Quadratzoll) ist.

15. Hämostatischer Stopfen nach Anspruch 14, wobei das Kollagen eine Dichte von 0,0057 bis 0,0059 gcm^{-2} (0,037 bis 0,038 Gramm je Quadratzoll) aufweist.

Revendications

1. Procédé de fabrication d'un tampon hémostatique (10) destiné à être mis en place au niveau d'un site où un traitement hémostatique est indiqué, ledit procédé consistant à enrouler une feuille (12) en matériau hémostatique d'une longueur prédéterminée sur plusieurs tours sur un outil de formage généralement cylindrique (32) de manière à produire ainsi un tampon hémostatique enroulé (10) ayant une ouverture (16) le long de son axe longitudinal, puis à retirer le tampon hémostatique enroulé (10) de l'outil de formage (32), caractérisé en ce que ce procédé comprend une compression longitudinale du tampon hémostatique enroulé (10) avant son retrait de l'outil de formage (32), de sorte que le tampon hémostatique est d'une longueur comprimée inférieure à la dimension de longueur prédéterminée.

2. Procédé selon la revendication 1, dans lequel la compression longitudinale comprend la réalisation d'un biseau (15) à l'extrémité distale du tampon (10) selon un angle compris entre 10 degrés et 45 degrés.

3. Procédé selon la revendication 1 ou la revendication 2, dans lequel le matériau hémostatique est choisi dans le groupe comprenant le collagène, la gélatine hémostatique, les matériaux à base d'acide polyglycolique modifié et la thrombine.

4. Procédé selon la revendication 3, dans lequel le matériau hémostatique est le collagène.

5. Procédé selon la revendication 4, dans lequel l'épaisseur de la feuille de collagène est de 0,0254 cm (0,010 pouce) à 0,0508 cm (0,020 pouce).

6. Procédé selon la revendication 5, dans lequel l'épaisseur est de 0,0356 cm (0,014 pouce) à 0,0406 cm (0,016 pouce).

7. Procédé selon la revendication 4, dans lequel la densité de la feuille de collagène est de 0,0050 à 0,0065 $g \cdot cm^{-2}$ (0,032 à 0,042 grammes par pouce carré).

8. Procédé selon la revendication 7, dans lequel la densité de la feuille de collagène est de 0,0057 à 0,0059 $g \cdot cm^{-2}$ (0,037 à 0,038 grammes par pouce carré).

9. Tampon hémostatique destiné à être mis en place dans le site d'une plaie où un traitement hémostatique est indiqué, le tampon comprenant au moins une feuille en matière hémostatique d'une dimension de longueur prédéterminée, ladite feuille étant enroulée sur elle-même plusieurs fois afin de créer une structure tubulaire, caractérisé en ce que ladite structure tubulaire est d'une longueur comprimée inférieure à ladite dimension de longueur prédéterminée, et ayant une ouverture sur toute la longueur comprimée de son axe longitudinale.

10. Tampon hémostatique selon la revendication 9, dans lequel une extrémité de ladite structure tubu-

laire est biseautée selon un angle compris entre 10 degrés et 45 degrés.

11. Tampon hémostatique selon la revendication 9 ou 10, dans lequel le matériau hémostatique est choisi dans le groupe comprenant le collagène, la gélatine hémostatique, les matériaux à base d'acide polyglycolique modifié et la thrombine.

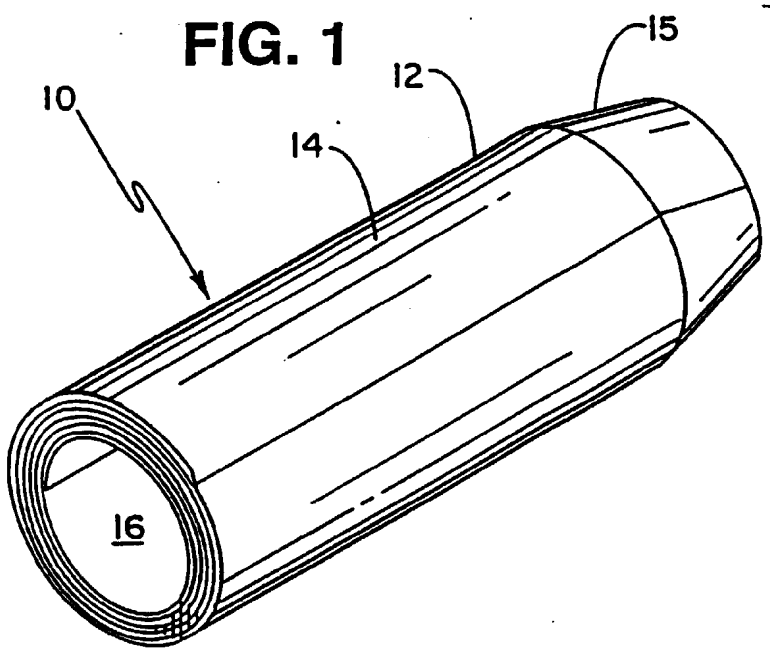
12. Tampon hémostatique selon la revendication 11, dans lequel le matériau hémostatique est le collagène.

13. Tampon hémostatique selon la revendication 9, dans lequel le tampon est constitué d'une feuille unique en matière hémostatique ayant sensiblement une densité unique.

14. Tampon hémostatique selon la revendication 13, dans lequel le matériau hémostatique est du collagène ayant une densité de 0,0050 à 0,0065 $g \cdot cm^{-2}$ (0,032 à 0,042 gramme par pouce carré).

15. Tampon hémostatique selon la revendication 14, dans lequel le collagène possède une densité de 0,0057 à 0,0059 $g \cdot cm^{-2}$ (0,037 à 0,038 gramme par pouce carré).

FIG. 1



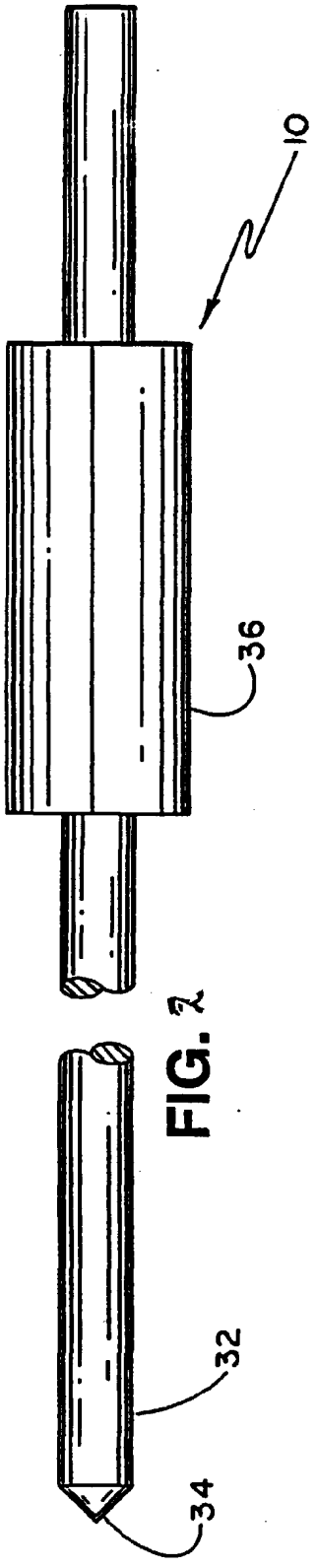


FIG. 2

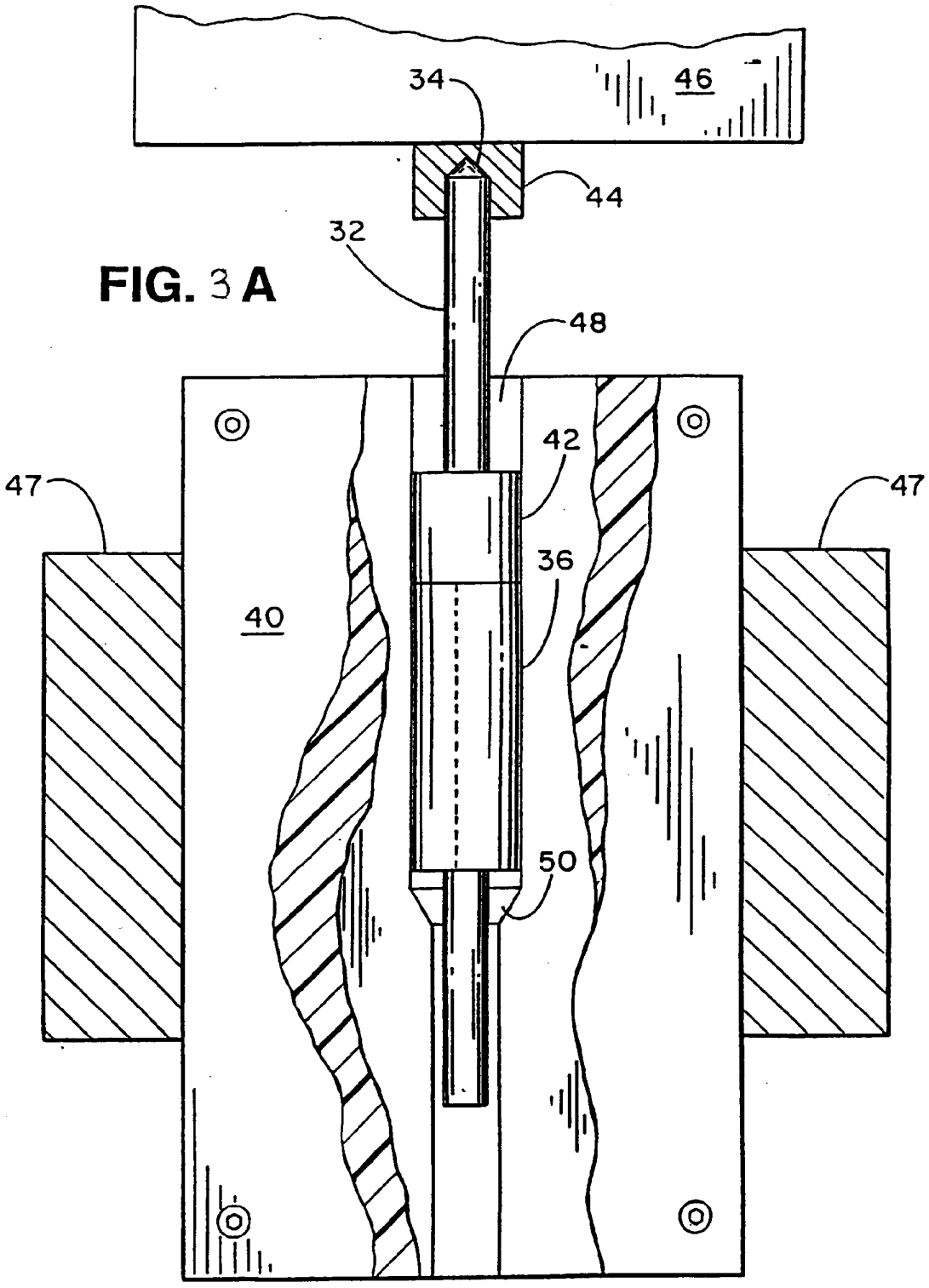


FIG. 3 A

FIG. 3B

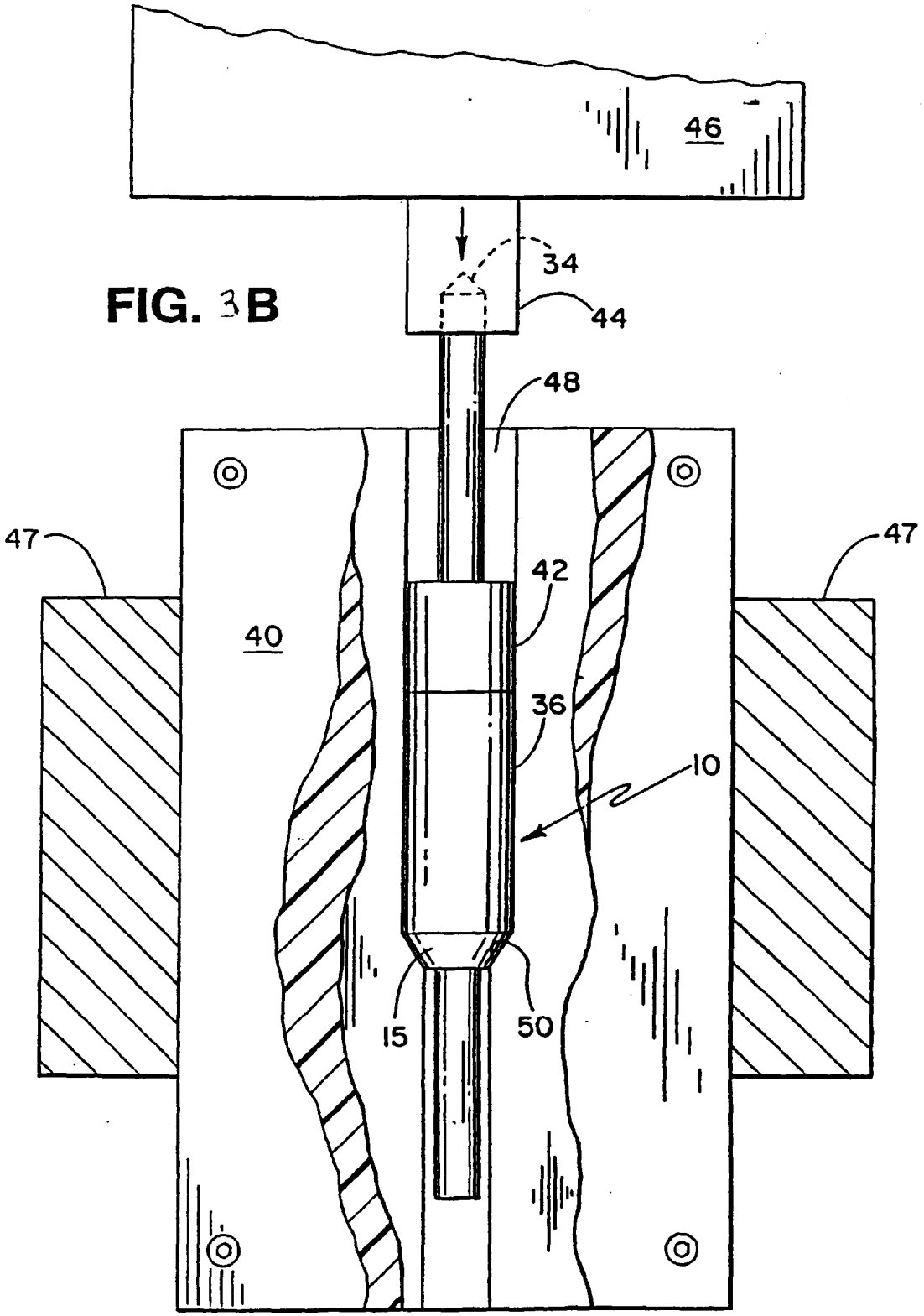


FIG. 4A

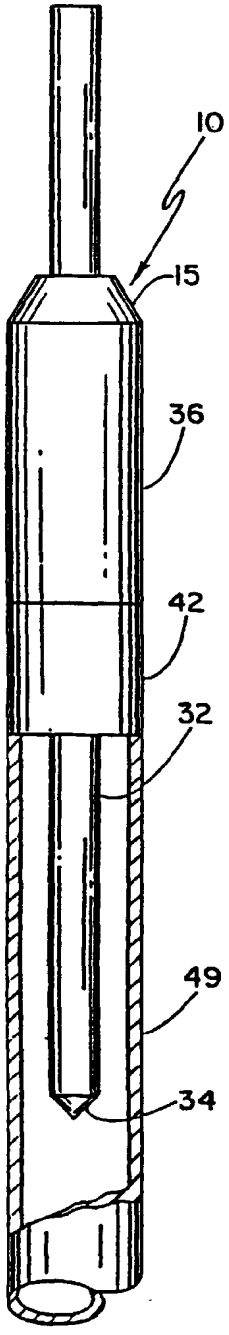
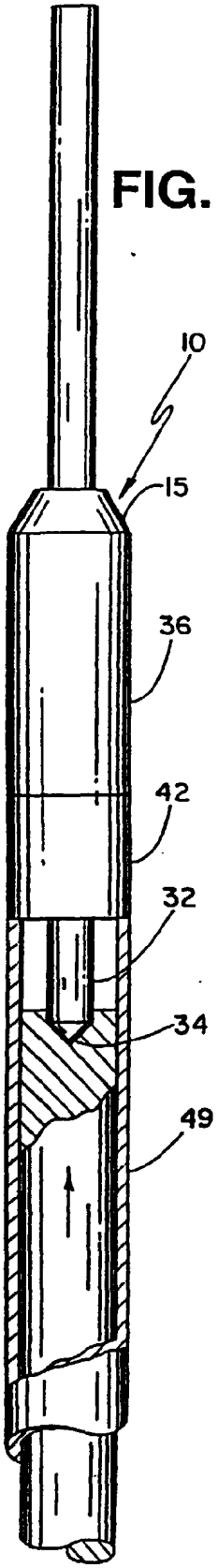


FIG. 4B



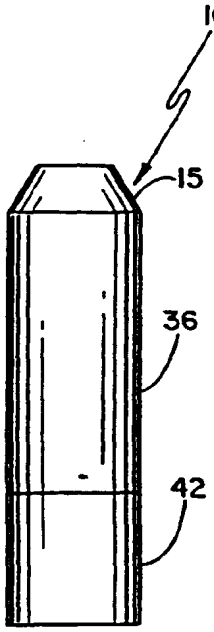


FIG. 4C

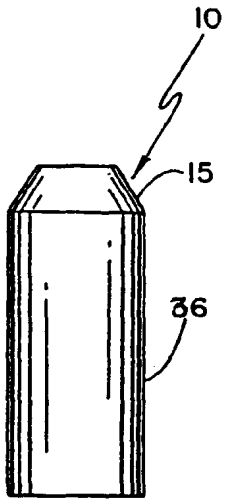


FIG. 4D

FIG. 5